

**AMENDMENTS TO THE DRAWINGS**

Two replacement sheets are attached hereto in attached Appendix 1A. One replacement sheet is a replacement sheet for the sheet of drawings containing FIG. 1. In that replacement sheet, FIG. 1 now includes the label “Prior Art”. The other replacement sheet is a replacement sheet for the sheet of drawings containing FIG. 2a. In that replacement sheet, FIG. 2a now shows an electrode 38 mounted on elongate member 30.

## **REMARKS**

1. In response to the Office Action mailed March 18, 2009, Applicants respectfully request reconsideration. Claims 1-8, 10-17 and 19-33 were last presented for examination. In the outstanding Office Action, claims 1-8, 10-13, 15-17, 19-24, 26 and 30-32 were rejected. By the foregoing Amendments, claims 1-4, 12-17, and 20-26 have been amended. Claims 34-43 have been added, and claims 5-8, 10-11, 19, and 27-33 have been cancelled. No new matter has been added. Thus, upon entry of this paper, claims 1-4, 12-17, 20-26, and 34-43 will be pending in this application. Of these twenty-seven (27) claims, 4 claims (claims 1, 12, 20, and 28) are independent.
2. Based upon the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

### *Art of Record*

3. Applicants acknowledge receipt of form PTO-892 listing additional references identified by the Examiner.
4. Applicants also thank the Examiner for returning form PTO/SB/08a submitted by Applicants on June 20, 2005, which has been initialed by the Examiner indicating that the Examiner has considered the references cited therein.
5. Although not relied upon by the Examiner, U.S. Patent No. 6,266,568 to Mann et al. was cited in paragraph 31 of page 10 of the outstanding Office Action. However, the Examiner did not list that patent in the PTO-892 form accompanying the Office Action. Accordingly, Applicants request that the Examiner make U.S. Patent No. 6,266,568 to Mann et al. of record in this application by issuing a new PTO-892 form listing that patent.

***Priority Claim***

6. Applicants note with appreciation the Examiner's acknowledgement of Applicants' claim of foreign priority under 35 U.S.C. §119, and for indicating that certified copies of the priority documents have been received from the International Bureau.

***Drawings***

7. The Examiner has objected to FIG. 1 because it does not contain the label "Prior Art." (*See*, Office Action, pg. 2.) Attached hereto in Appendix 1A is a replacement sheet for former FIG. 1. In this replacement sheet, FIG. 1 now includes the label "Prior Art".

8. The Examiner has also objected to the drawings for not illustrating "a resiliently flexible elongate member having... a distal end," an "adhesive" or "a material that swells on contact with fluids." (*See*, Office Action, pg. 2.) To facilitate prosecution of this application, Applicants have amended the claims to remove recitation of "a distal end" of "a resiliently flexible elongate member," an "adhesive" and "a material that swells on contact with fluids."

9. The Examiner has also objected to the drawings for failing to show "at least one electrode" mounted on an elongate member. (*See*, Office Action, pg. 2.) Attached hereto is a replacement sheet for the sheet of drawings containing FIG. 2a. In that replacement sheet, FIG. 2a includes a schematic illustration of an electrode 38 mounted on elongate member 30 in one exemplary location. Applicants submit that no new matter is added.

10. As stated in 37 CFR 1.83(a), "conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box)." (*See*, 37 CFR 1.83(a)). As such, Applicants submit that electrode 38 is sufficiently illustrated in FIG. 2a.

11. In view of the above, Applicants request that the objections to the drawings be reconsidered and that they be withdrawn.

***Claim Objections***

12. The Examiner has objected to claims 5-7, 11, 14, and 19 for various informalities. Applicants have cancelled claims 5-7, 11 and 19 and, as such, assert that the objections to these claims have been rendered moot.

13. Applicants have amended claim 14 to recite “that substantially matches a shape of,” as recommended by the Examiner. As such, Applicants respectfully request that the objection to claim 14 be withdrawn.

***Allowable Subject Matter***

14. Applicants thank the Examiner for indicating that claims 14, 15-17, 25-29 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claims.

***Claim Rejections under §112, First Paragraph***

15. The Examiner has rejected claims 8, 10, 11 and 27 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants have cancelled claims 8, 10, 11 and 27, thereby rendering the rejections of these claims moot.

16. The Examiner has also rejected claims 20-24 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner asserts that Applicants' disclosure does not describe an embodiment comprising both “a sealing member,” as recited in claim 12, and “a compression member,” as recited in claims 20-24. (See, Office Action, pg. 4.) Applicants claims 20-24, as amended, no longer depend from claim 12, and therefore do not include both “a sealing member” and “a compression member.” Accordingly, Applicants request that the rejections of claims 20-24 under 35 U.S.C. 112, first paragraph be withdrawn.

***Claim Rejections under §112, Second Paragraph***

17. The Examiner has also rejected claims 2, 7, 11, 15-17, 19 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which Applicant regards as the invention. Specifically, the Examiner has rejected claim 2 because the Examiner asserts that neither of claims 1 and 2 positively recite “a stiffening element.” (See, Office Action, pg. 5.) The Examiner alleges that “[i]t is sufficiently unclear whether or not Applicant intends to claim a device as defined by Claim 1 where the device further comprises ‘a stiffening element’.” (See, Office Action, pg. 5.) To facilitate prosecution of this application, Applicants have amended claim 1 to positively recite a “stiffening element.” As such, Applicants respectfully request that the rejection of claim 2 be withdrawn.

18. The Examiner has also rejected claim 7 because there is allegedly insufficient antecedent basis for the limitation “the stiffening element.” (See, Office Action, pg. 5.) The Examiner also states that it is sufficiently unclear if the “seal” in claim 7 is the “sealing member” recited in claim 19. (See, Office Action, pg. 5.) Applicants have cancelled claim 7, thereby rendering these rejections moot.

19. The Examiner has further rejected claim 15 (and claims 16 and 17, which depend from claim 15) as lacking antecedent basis for the feature “said distal end.” (See, Office Action, pg. 5.) As amended, claim 15 recites “a distal end” rather than “said distal end.” (See, Applicants’ claim 15, above.) In addition, the Examiner has rejected claim 26 because it is unclear whether the limitation “at least one first portion” is the same as the “first portion having a first diameter.” (See, Office Action, pg. 5.) (See, Office Action, pg. 5.) Applicants have amended claim 26 to replace “at least one first portion” with “said third portion.” For at least these reasons, Applicants request that the rejections of claims 15-17, 19 and 26 under 35 U.S.C. 112, second paragraph, be reconsidered and that they be withdrawn.

#### ***Claim Rejections under §102 in view of Kuzma***

20. The Examiner has rejected claims 1-8, 10-13, 19-23, 31 and 32 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,315,763 to Kuzma et al. (hereinafter, “Kuzma”). Applicants respectfully disagree.

21. Kuzma is directed to “a cochlear electrode design having a curved electrode array for insertion into a cochlear cavity.” (See, Kuzma, col. 3, lns. 57-60.) Kuzma teaches “an

improved stimulation lead for implanting into a body cavity.” (*See*, Kuzma, col. 3, lns. 61-62.) The lead “includes a stylet insertion channel which is used during implantation of the lead to help guide the lead into a cavity.” (*See*, Kuzma, col. 4, lns. 34-36.)

22. Kuzma also teaches that “an overmold can be attached over the opening of the stylet insertion channel,” and that “[a] tip of an insertion stylet 77 can be inserted through” a slit in the overmold and “into the stylet insertion channel.” (*See*, Kuzma, col. 4, lns. 61-62, and col. 13, lns. 26-28.) Kuzma also discloses that “a malleable ring . . . may be formed into the overmold” to encircle the slit. (*See*, Kuzma, col. 5, lns. 14-15, and col. 13, lns. 17-18.) The “ring may be crushed around the slit to provide a compression seal.” (*See*, Kuzma, col. 5, lns. 14-15, and col. 13, lns. 17-18.)

### ***Claim 1***

23. Applicants respectfully assert that Kuzma fails to teach “[a]n implantable tissue-stimulating device” comprising a lumen and “***a seal disposed in said lumen*** and configured to be pierced by said stiffening element,” as recited in Applicants’ claim 1, above. (Emphasis added.) As discussed above, Kuzma discloses that “an overmold can be attached ***over*** the opening of the stylet insertion channel.” (*See*, Kuzma, col. 4, lns. 61-62; emphasis added.) As shown in FIGS. 4 and 5 of Kuzma, the overmold is “used to ***cover*** the end opening 50 of the stylet insertion channel 40.” (*See*, Kuzma, col. 4, lns. 61-62; emphasis added.) Therefore, Applicants assert that Kuzma teaches only that an overmold may be disposed over an opening in a stylet insertion channel, but fails to disclose “***a seal disposed in said lumen***,” as recited in claim 1.

24. For at least the reasons detailed above, Applicants assert that Kuzma fails to anticipate the invention recited in claim 1. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. §102 be reconsidered, and that it be withdrawn.

### ***Claim 12***

25. Applicants’ claim 12 is directed to “[a]n implantable tissue-stimulating device” comprising a lumen and “a sealing member ***mounted to, and moveable with, a section of said stiffening element within said lumen***.” (*See*, Applicants’ claim 12, above; emphasis added.) In

the outstanding Office Action, the Examiner states that “when the stiffening element 77 of Kuzma ‘763 is positioned within lumen 40 of the device 150, the seal/sealing member 75 is considered to be mounted to the stiffening element 77 since the stiffening element is inserted through slit 76 of the seal/sealing member 75.” (See, outstanding Office Action, pg. 7.) Applicants respectfully disagree.

26. Specifically, Applicants submit that overmold 75 is not equivalent to the “sealing member” recited in claim 12 because the overmold is not “mounted to and **moveable with**” a stiffening element as recited in claim 12. (Emphasis added.) As stated above, the stylet of Kuzma is inserted through a slit of the overmold, and the stylet is free to move through the slit. (See, Kuzma, col. 4, lns. 61-62, and col. 13, lns. 26-28.) It should be appreciated that in order to prevent fluid and/or bacteria from entering the stylet insertion channel, the movement of the stylet through the slit of Kuzma must not disturb the location of the overmold. Therefore, the overmold is not “mounted to and **moveable with**” the stylet.

27. For at least the reasons detailed above, Applicants assert that Kuzma fails to anticipate the invention recited in claim 1. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. §102 be reconsidered, and that it be withdrawn.

### ***Claim 20***

28. Applicants’ claim 20 is directed to “[a]n implantable tissue-stimulating device” comprising a lumen and “a compression member mountable around at least a portion of said elongate member . . . wherein said compression member is adjustable between a first configuration in which said compression member does not compress any portion of said lumen **and a second configuration in which said compression member compresses at least a first portion of said lumen.**” (See, Applicants’ claim 20, above; emphasis added.) As discussed above, Kuzma teaches “a malleable ring” formed into the overmold and so as to encircle the stylet receiving slit. (See, Kuzma, col. 5, lns. 14-15, and col. 13, lns. 17-18.) The “malleable ring” may be crushed around the slit to seal the slit. (See, Kuzma, col. 5, lns. 14-15, and col. 13, lns. 17-18.) Applicants assert that the malleable ring of Kuzma is not equivalent to the “compression member” recited in claim 20 because the malleable ring is not “**mountable around** at least a portion of said elongate member,” nor does it compress “at least a first **portion**

*of said lumen*" within the elongate member. (See, Applicants' claim 20, above; emphasis added.) For at least these reasons, Applicants assert that Kuzma fails to anticipate all elements of claim 20. Therefore, Applicants respectfully request that the rejection of claim 20 be reconsidered and that it be withdrawn.

### ***New Claims***

29. Applicants' new claim 37 is directed to a method "of placing an implantable tissue-stimulating device in a body of an implantee, the device comprising . . . a sealing member mounted to, and moveable with, a section of the stiffening element within said lumen." (See, Applicants' claim 37, above.) The method comprises "at least one of during and after insertion of the elongate member, moving the stiffening element from a first position in which the sealing member does not seal the lumen to a second position in which the sealing member substantially seals the lumen." (See, Applicants' claim 37, above.) As noted above, Kuzma fails to disclose a device in which a sealing element is "mounted to, and moveable with, a section of the stiffening element." As such, Applicants' assert that Kuzma cannot disclose moving such a stiffening element/sealing member combination "from a first position in which the sealing member does not seal the lumen to a second position in which the sealing member substantially seals the lumen" as recited, in part, in claim 37. For at least these reasons, Applicants assert that Kuzma fails to anticipate all elements of claim 37.

### ***Dependent Claims***

30. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

***Conclusion***

31. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

32. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of the above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

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Respectfully submitted,

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## **APPENDIX 1A**